R E M A R K S

This submission is in response to the *Final Office Action* that issued on June 9, 2010, and is further accompanied by a *Request for Continued Examination (RCE)*. Additionally, the applicants submit that the filing of this RCE is to withdraw the instant application from appeal.

Claims 11-3, 17-23, 25, and 28-30 were presented for examination and were rejected. The applicants respectfully request reconsideration of the instant application in light of the following comments.

Applicants' Remarks in Regard to "Response to Amendment" Section

Under the section *"Response to Amendment"* of the *Non-Final Office Action* that issued on October 13, 2009, the Examiner rejected the experimental data put forth in a *Declaration* by the applicant, Robert Gordon Hood, to demonstrate that the stent of the current claims elutes more drug than a standard stent — *i.e.,* one without a helical insert.

The Examiner is of the opinion that *"it is difficult to distinguish to what extent the difference in elution is due to the spiral configuration or the aspirin load in order to determine if the results are entirely unexpected."* (see, page 2 of the Non-Final Office Action that issued on October 13, 2009).

It is respectfully requested that the Examiner reconsider this assertion taking into account the information provided in *"Annex 1"* submitted herewith. The information provided in "Annex 1" regards the effective surface area of the stent of the present invention and that of a standard control stent without a helical insert.

In summary, there is a surprising technical advantage in delivering drugs from the stent of the present invention that is neither disclosed nor suggested by the prior art. It is submitted that the stent of the present invention elutes more of the coated drug further downstream than a standard stent without a helical insert. It asserted that the improvement in drug elution arises as a result of the helical insert and not due to some other difference, such as increased drug loading, between the stent of the present invention and the control stent that were tested.

The Declaration signed by the applicant, describes a set of experiments, wherein the applicant compared the drug elution ability of the stent of the present invention with that of

a standard stainless steel stent lacking a helical insert. Each stent was tested in a control rig. Water was passed through each stent and the water runoff was collected in a collection tank. Samples were taken from the tank and analyzed. The coating of the testing drug, aspirin, was suspended in medical grade polyurethane dilution. The coating was identical on both of the stents, the stent of the present invention and standard control stent. Both stents were dipped in the solution identical times and air dried. As further outlined in "Annex 1," the effective surface area of both stents has been compared. The surface area measurements of stent structure were based on a close approximation of the length of each wire, excluding the welded junctions and the deformation of the wire at each junction. In the surface area of both, the stent exposed surface to the flow of the fluid was regarded as approximately 50% of the effective surface area of stent of the current invention was 11 cm^2, whereas the effective surface area of the standard control stent was 9.4 cm^2. There is, therefore, a difference in effective surface area of only 1.6 cm^2 between the two stents.

As outlined under *"section 17"* of the Declaration, the stent of the present invention eluted on average 71% more aspirin than the standard control stent. In addition, as outlined under *"section 15"* and *"section 16"* of the Declaration, drug elution was measured at distances of 5 cm distal to the stent. The stent of the present invention has an effective surface area which is only 1.6 cm, *i.e.,* 17%, larger than a standard stent but yet elutes 71% more drug than a standard stent at distances 5 cm downstream from the stent. Although the stent of the present invention comprises a greater load of drug, the effective surface area is only 1.6 cm, *i.e.,* 17%, larger than a standard stent and, therefore, the elution characteristics are disproportionally better than expected. The increased elution of drug from the current stent to areas downstream from its distal end is not due solely to the increased loading of the drug on the stent but due to the presence of the helical insert. Therefore, the increase elution of drug would have been unexpected to a person skilled in the art, even if the relative surface areas of the respective stents had been calculated and taken into account. This information provides further evidence of the unexpected enhanced drug elution ability of the current stent claimed in the instant application.

35 USC § 112, Second Paragraph Rejection of Claim 21

Claim 21 was rejected under 35 USC § 112, Second Paragraph because the Examiner asserts that the limitation *"the intravascular stent insert is a stent graph"* is indefinite.

More specifically, the Examiner asserts that *"the recitation [of] 'the intravascular stent insert is a stent graph' is unclear since the specification of the instant application states that the intravascular stent includes an stent insert as a stent-graft."*

In response to the rejection, claim 21 has been amended to recite that *"the intravascular stent can be a stent graft"*; as opposed to *"the intravascular stent insert can be a stent graft"* that was previously recited in claim 21. In view of this amendment, the applicants respectfully submit that the rejection of claim 21 under 35 USC § 112, Second Paragraph is overcome.

35 USC § 103 Rejection of Claims 1-3, 17-23, 25, and 28-30

Claims 1-3, 17-23, 25, and 28-30 were rejected under 35 USC § 103 as being obvious over the combination of US Patent Application Publication No. 2003/0139807 (hereinafter "*Houston*"), US Patent No. 7,195,640 (hereinafter "*Falotico*"), and US Patent No. 6,159,239 (hereinafter "*Greenhalgh*"). The applicants respectfully traverse the rejection for the reasons discussed below.

Independent claim 1 recites:

> **1.** A drug delivery device comprising:
>
> a drug;
>
> *a wire mesh intravascular stent having a blood-contacting surface*;
>
> a stent insert comprising a helical formation, made from a polymer, on the blood contacting surface, *the helical formation comprising at least one fin and having a helix angle of between 8° and 20° and being capable of inducing helical flow of blood flowing past the helical formation, and the drug being releasably associated with the helical formation of the stent insert*.
>
> ***(emphasis supplied)***

Nowhere do Houston, Falotico, and Greenhalgh, whether considered individually or in any combination, teach, suggest, or motivate what claim 1 recites — namely, a drug delivery device comprising, *inter alia*:

- a wire mesh intravascular stent having a blood-contacting surface, and
- a stent insert comprising a helical formation … the helical formation comprising at least one fin and having a helix angle of between 8° and 20° and being capable of inducing helical flow of blood flowing past the helical formation, and the drug being releasably associated with the helical formation of the stent insert.

At page 3 of the Final Office Action, the Examiner states that *"Houston et al. fails to disclose a drug releasably associated with the helical formation and the formation having a helix angle of between 8° and 20°."* The applicants agree with the Examiner's statement.

The Examiner asserts, however, that Falotico and Greenhalgh cure the deficiencies of Houston with respect to these features of the present invention. More specifically, the Examiner is of the opinion that Falotico teaches a drug coated medical device and that Greenhalgh teaches a helix angle of between 8° and 20°. The Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time of the present invention, to provide a stent of the combination of Houston, Falotico, and Greenhalgh so as to obviate the drug delivery device of claim 1.

This rejection is respectfully traversed. As stated by the Courts time-over-time *"the mere fact that the prior art may be modified in the manner suggested by the Examiner <u>does not</u> make the modification obvious <u>unless</u> the prior art suggested the desirability of the modification."* (see, *In re Gordon, 733 F.2d at 902, 221 USPQ at 1127*).

In view of *In re Gordon*, it is submitted that a person skilled in the art would not be motivated to combine the teachings of Houston, Falotico, and Greenhalgh. Arguably, even if a person skilled in the art did combine the teachings Houston, Falotico, and Greenhalgh, the combination of the prior art teachings would not arrive at the drug delivery device of claim 1. Accordingly, the subject matter of the pending claims is not obvious in view of Houston, Falotico, and Greenhalgh, as further discussed below.

With respect to Falotico, the Examiner asserts that one of ordinary skill in the art would be motivated to provide with stent of Houston with the drug coating of Falotico to reduce inflammation and thrombosis. It is submitted, however, that Houston is silent as to any problems associated with the described stent. One of ordinary skill in the art would therefore not be motivated to alter the stent of Houston to reduce inflammation and thrombosis, as Houston has <u>not</u> reported any such complications or issues with their stent.

The Examiner further believes that one of ordinary skill in the art would combine Houston with the teachings of Greenhalgh to arrive at the drug delivery device of claim 1. The Examiner is of the opinion that one would adapt the teachings of Houston to produce a helical insert having a helix angle of between 8° and 20°. It is submitted that one of

ordinary skill in the art would not combine the device of Houston with that of Greenhalgh for a number of reasons.

Firstly, the Examiner has used the applicants claimed invention as an instruction manual to combine the teachings of Houston and Greenhalgh to arrive at the determination of obviousness. As stated by the Courts, *"[i]t is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."* (see, *In re Gorman, 933 F.2d 982, 987, 18 USPQ2s 1885, 1888 (Fed.Cir.1991)).* (see also, *In re Fine, 837 F.2d at 1075, 5 USPQ2d at 1600).*

In view of *In re Gorman* and *In re Fine*, it is submitted that the Examiner used impermissible hindsight construction to combine the stent member (26) of Greenhalgh with the helical insert described by Houston. More specifically, the feature of Greenhalgh to which the Examiner refers, namely stent member (26), is not a direct counterpart to the helical insert described by Houston. The stent member (26) has a different role to the helical insert. The stent member (26) has a structural role. The helical insert of Houston in contrast has no influence on the structure of the stent in which it is inserted. It is submitted that the helical insert of Houston is not a corresponding part to the stent member of Greenhalgh and, therefore, a person skilled in the art would have no rationale for substituting one part for the other.

Secondly, the main body of the device of Greenhalgh is a *"textile graft."* The stent member of Greenhalgh is woven within the textile graft and does not extend from the surface of the textile graft, *i.e.* does not contain at least one fin. In contrast, the helical insert of Houston is not woven but sits within the wire-mesh stent. The helical insert of Houston also contains at least one fin extending from its surface.

Arguably, even if one of ordinary skill in the art were to replace the helical insert of Houston with the stent member of Greenhalgh, the resulting device would no longer comprise a helical formation containing at least one fin which extends from the surface of the stent, which would completely defeat the purpose of the helical insert. Therefore it is submitted that one of would not arrive at the drug delivery device of claim 1. In further contrast to the present invention, even if a person skilled in the art were to combine the

helical insert of Houston with the device of Greenhalgh, the combination would no longer have a wire-mesh stent and, therefore, any device made from the combination would not fall within the scope of the claims. Moreover, such a device would no longer have the structural properties desired by Greenhalgh.

Finally, in relation to the teachings of Greenhalgh regarding the helix angle of the stent member — in this embodiment of Greenhalgh, the stent member is assigned (72) —, the applicants stress that Greenhalgh does not teach a helix angle of the claimed range and, in fact, teaches one of ordinary skill in the art away from said range. The applicants respectfully direct the Examiner's attention to column 13, paragraph 5 – column 14, paragraph 1 of Greenhalgh.

Greenhalgh states, at these passages, that in order to obtain substantially homogenous compressive and flexural properties a range of "*10 degrees to about 85 degrees is preferable* ***with a range of about 45 degrees to about 85 degrees believed to be somewhat more preferable. A value of about 82 degrees is presently believed to be most preferable***." Greenhalgh's preference for a value of 82° is far and removed from the range of claim 1.

In addition, the problem to be solved by the range of claim 1 is not the same problem that is being solved by Greenhalgh. Greenhalgh states that a range of 10° to 85° is preferable to obtain homogenous compressive and flexural properties for the structure; whereas, and in contrast, the fin of the helical insert of claim 1 has a helix angle between 8° and 20° to reduce turbulent flow and dead flow in blood. As the drug delivery device of claim 1 is a wire-mesh stent, wherein the polymer fin plays no structural role. In addition, it is stressed by the applicants that the stent member (72) of Greenhalgh is not a counterpart for the fin of the helical insert of Houston.

Therefore, it is submitted that one of ordinary skill in the art is only taught by Greenhalgh that a helix angle of 82° achieves the desired structural properties. When looking to reduce turbulent blood flow, one of ordinary skill in the art would not look to Greenhalgh for a solution nor would one find a solution in Greenhalgh. Arguably, even if one of ordinary skill in the art were to impart a helical angle as taught by Greenhalgh to the fin of the helical insert of Houston, they would arrive at a device that caused turbulent flow in blood. (see, specification page 2, lines 14-15). The inventors of the present invention

have previously outlined the deficiencies of stents, such as the one disclosed in Greenhalgh, at page 2, lines 14-15 of the specification.

In conclusion, the helical insert of Houston is not a direct counterpart for the stent member of Greenhalgh. The parts do not serve the same function and a person skilled in the art would have no motivation to substitute one for the other. Arguably, even if the device of Houston was combined with that of Greenhalgh, any resulting device would fall outside the scope of the claim 1.

For at least the reasons discussed above, Falotico and Greenhalgh fail to cure the deficiencies of Houston. As a consequence, claim 1 is allowable over Houston, Falotico, and Greenhalgh, whether considered individually or in any combination.

Since claims 2, 3, 17-23, 25, and 28-30 depend on claim 1, and because claim 1 is believed to be allowable for the reasons presented, these dependent claims are likewise allowable. Moreover, the recitation of additional patentable features recited in these dependent claims provides an additional basis for their patentability.

No Waiver

All of the applicants' arguments are without prejudice or disclaimer. The applicants reserve the right to discuss the distinctions between the applied art and the claims in a later Response or on Appeal, if appropriate. By not responding to additional statements made by the Office, the applicants do not acquiesce to the Office's additional statements. The distinctions discussed by the applicants above are sufficient to overcome the rejections.

Request for Reconsideration Pursuant to 37 CFR § 1.111

Having responded to each and every ground for objection and rejection in the last Office action, applicants respectfully request reconsideration of the instant application pursuant to 37 CFR § 1.111 and request that the Examiner allow all of the pending claims and pass the application to issue.

If there are remaining issues, the applicants respectfully request that Examiner telephone the applicants' agent so that those issues can be resolved as quickly as possible.

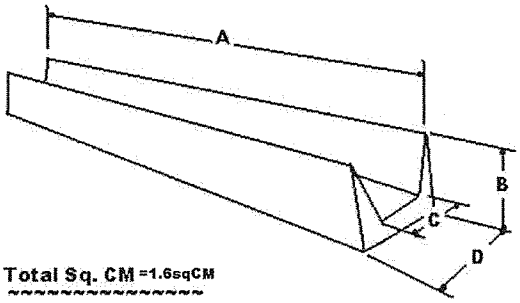
Respectfully,
Robert Gordon Hood et al.

By **/Henry Vuu/**
Henry Vuu
DeMont & Breyer, LLC
Agent for Applicants
Reg. No. 62865
732-578-0103 x224

DeMont & Breyer, L.L.C.
Suite 250
100 Commons Way
Holmdel, NJ 07733
United States of America

ANNEX 1

SURFACE AREA OF BOTH STENT AND SPIRAL STENT FOR DRUG DELIVERY.



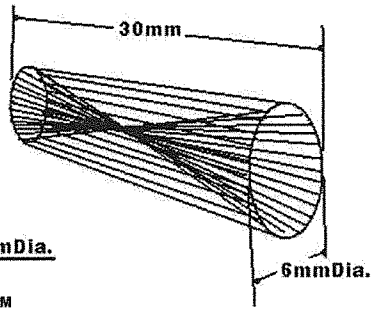
A 30mm(30°)

B 1·4mm

C 2mm

D 2.5mm

Total Sq. CM =1.6sqCM



(ñ d h. ñ = 3.142)

S.S. wire stent with welded junctions.
Total of 20 wires 1mmDia.

Total Sq. CM = 9·4sqCM

Total for control stent = 9.4sq CM

Total for spiral stent = circa 11.0 sq CM